

Applicants : Seetharama A. Acharya and Belur N. Manjula  
Appn. No. : 10/538,976  
Filing Date : December 5, 2005  
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#### REMARKS

Claims 8-21 are pending in the subject application. By this amendment, Claims 8-16 have been amended. Applicants maintain that the claim amendments do not raise an issue of new matter. Support for the term “fold molar excess” can be found, for example, on page 3 of the application as filed. Support for the term “on average” can be found at least on page 26, paragraph [0072], line 2; page 13, paragraph [0047], last 2 lines; and page 23, paragraph [0066]. Entry of the amendments is respectfully requested.

#### Objections to the Claims

Claims 8-21 are objected to for reciting “fold excess,” which the Examiner recommended be amended to recite “fold molar excess.” The claims have herein above been amended as recommended by the Examiner, thereby obviating this objection.

#### Rejections under 35 U.S.C. §103(a)

Claims 8-21 are rejected as being unpatentable over Acharya et al. (U.S. Patent No. 6,017,943) in view of Nho et al. (U.S. Patent No. 5,234,903).

Applicants respectfully traverse this rejection.

Applicants understand that this rejection is predicated on the Examiner’s interpretation of the language of Claim 8 as open-ended and to mean a process for preparing a Hb with *at least* - but not limited to - six  $\pm$  one PEGs. Claim 8 has herein above been amended to clarify that the modified Hb has on average six  $\pm$  one PEG chains.

Applicants maintain that the cited references do not teach or suggest the claimed method for preparing a hemoglobin molecule (Hb) modified to have on average six  $\pm$  one PEG chains, where the method comprises the steps of:

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- (a) reacting Hb with 8-15 fold molar excess of iminothiolane to form thiolated Hb; and
- (b) reacting the thiolated Hb with 16-30 fold molar excess of PEG functionalized with a maleimide moiety, to form the modified Hb having on average six  $\pm$  one PEG chains.

In addition, the cited references do not provide a motivation for attempting to produce a Hb with six  $\pm$  one PEG chains, since it was not determined until the present invention that the PEGylated Hb produced by the claimed method has advantageous, non-hypertensive properties.

Reconsideration and withdrawal of this rejection are respectfully requested.

#### Provisional Obviousness-Type Double Patenting Rejection

Claims 8-21 are provisionally rejected over Claims 27 and 29 of co-pending U.S. Patent Application No. 11/921,064. Since the present application is earlier filed than Application No. 11/921,064, withdrawal of this provisional rejection is respectfully requested upon withdrawal of the rejection under 35 U.S.C. §103(a) discussed above (MPEP §804).

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CONCLUSIONS

In view of the amendments and remarks made hereinabove, reconsideration and withdrawal of the objection and rejections set forth in the July 9, 2008 Office Action and passage of the pending claims to allowance are respectfully requested. If there is any minor matter preventing the allowance of the subject application, the Examiner is requested to telephone the undersigned attorney.

No fee is deemed necessary in connection with the submission of this reply. However, if any fee is required to maintain the pendency of the subject application, authorization is hereby given to withdraw the amount of any such fee from Deposit Account No. 01-1785.

Respectfully submitted,  
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New York, New York

By   
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